Department	Research & Development
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This page details the version history and the main changes made for each new version.

Version Log		
Version number and date	**Author**	**Details of significant changes**
Version 1, 14.02.21	J Illingworth & S Moffat	First SOP approved by R&D Committee on 30.06.2021
Version 2, 11.04.2024	G. Constable	-Section 6: Vendor Selection and Computer System Validation (CSV), added to SOP. -R&D replaced with RDI (research development and innovation) in-line with current department name.

Please note for definitions of acronyms refer to Appendix 1 of Management of SOPs. Refer to Appendix 2 of Management of SOPs for the standards to which clinical trials that investigate the safety and/or efficacy of a medicinal product are conducted.

All the HUTH R&D GCP SOPs are available at:
https://www.hey.nhs.uk/research/researchers/gcp-sops-for-hey-sponsored-ctimps/

1. Purpose

The purpose of this SOP is to describe the Sponsor/Chief Investigator/Principal Investigator responsibility of following the process to select a suitable third party vendor for a specific delegated trial activity and the contracting and oversight when the vendor has been chosen. A vendor is a person, organisation or agency external to HUTH that provides functions, services or products related to the conduct of research sponsored by HUTH. It does not include research collaborators or other research sites.

2. Who should use this SOP

This SOP should be used by:

- All HUTH RDI staff who manage the sponsorship of HUTH-sponsored CTIMPs.
- Research staff involved with clinical trials sponsored by an external organisation where the sponsor has no SOP for vendor assessment. HUTH R&D SOPs are defaulted to in this case.
- Research staff involved with HUTH-sponsored non-CTIMPs.

3. Background

Sponsors do not perform all trial activities in-house and often use external vendors, such as Contract Research Organisations, Clinical Trials Units, laboratories, randomisation services, IMP procurement and management.

The sponsor must follow a process for the selection of a suitable vendor.
Sponsors should ensure that an adequate assessment of suitability of a vendor is carried out before contracts are signed. This process must be documented and the rationale for selection must be clear.

It should be noted that although the sponsor retains complete responsibility for the clinical trial, all vendors must show due diligence when performing delegated trial activities and all persons involved in the conduct of a clinical trial have a legal responsibility to comply with GCP, the protocol and the terms of the MHRA CTA and REC favourable opinion.
The Medicines for Human Use (Clinical Trials) Regulations 2004, Regulation 28 (1) of SI 2004/1031 and Regulation 29 of SI 2004/1031.

4. Vendor selection

The requirement for the use of external vendors must be identified during the development of the study protocol and/or grant application submission as part of the sponsor risk assessment following the CI completing the sponsorship request form. The cost of using an external vendor must also be factored into the grant application.

Where a grant application requires costings for a Clinical Trials Unit (CTU), the CTU may be chosen by the CI before any contracting takes place.

The CI must ensure appropriate processes are followed when selecting an external vendor and must liaise with the RDI Office to ensure appropriate risk assessment and contract negotiations can take place.

RDI will ensure there is due diligence and a background check to ensure that the vendor chosen is suitable for the required task requested, is a viable vendor and is value for money before any contracting is entered into.

Where possible the CI should choose 3 vendors for price and service delivery comparison. A choice should not be made on price alone if the service is not comparable to the other vendors.

A comparison of 3 vendors is not necessary if for example the CI has used a service before and can recommend it or it is a specialist service not widely available.

The intention of the sponsor is to consolidate a list of preferred vendors however the listed vendors will still be assessed on a study by study basis.

The sponsor is ultimately responsible for all activities outsourced to an external vendor.

Where specialist services are being contracted, the CI and sponsor will liaise with the relevant expertise and support services (i.e. HUTH Clinical Trials Pharmacy Team).

A risk based approach to the selection of vendors should be adopted. The CI and RDI Office will need to look at the risks associated with the tasks to be delegated as well as previous experiences and intelligence on the vendor (i.e. has the CI or Trust used the vendor in other work).

5. Vendor assessment

Vendor assessment methods include:

- Assessment questionnaires
- Assessment of CVs and previous experience
- Obtaining suitable references
- Referring to prior knowledge from use in other trials
- Assessing quality systems/written procedures/SOPs
- Conducting independent audits

RDI QA will send out a Vendor Assessment Questionnaire (VAQ) to the selected vendors using the appropriate questionnaire (i.e. CTU, laboratory or IMP manufacturer).

On return of the completed questionnaire and any relevant documentation (i.e. SOPs, written procedures, CVs, training records) requested by the sponsor, RDI QA will review these or ask colleagues in the relevant specialist areas to do so on their behalf.

Any anomalies will be identified and raised with the vendors.

An assessment will be considered complete when all documents requested have been received, any queries answered.

The decisions made to select a vendor must be documented and held in the TMF.

6. Vendor Selection and Computer System Validation (CSV)

When selecting vendors for clinical trials, it is essential to consider the validation requirements for computerized systems. These systems play a crucial role in capturing, processing, analysing, and reporting clinical trial data. As a sponsor, we must ensure that these systems are "fit for purpose," particularly when they impact the quality of trial data and subject safety. Properly validated systems ensure accurate data capture, processing, and reporting, minimizing the risk of protocol breaches and ensuring compliance with Good Clinical Practice (GCP) and relevant legislation. By rigorously assessing and validating vendor systems, we safeguard the integrity of clinical trial data, contributing to the overall success of our research endeavours.

All considerations should be documented with reference to specific software being used; including a reference to the version of software being considered, as these can change over time. Furthermore it is important that not only the product itself should be reviewed and validated but the any trial-specific configurations.

WI 24 provides a Computer System Validation review that should be used to document the review of software being proposed and should form part of the overall study risk assessment. The completed CSV should be signed off a reviewed within the RDI QA department (for example through Docusign) to provide a static and can be referred to throughout the study. A completed CSV report should be used to guide the study's monitoring plan in line with the overall study risk assessment.

Examples of such systems include operating system databases (such as those dedicated to the collection, processing, reporting and storing of equipment data used in a study), electronic Case Report Form (eCRF) systems, clinical trial databases, electronic data transfer tools, electronic diaries for subjects, and electronic trial master files. NB: for study databases *R&D GCP SOP 13 Data management* should be used.

Systems that are used routinely in standard of care within the trust (HUTH) may not require a CSV when completing sponsorship assessments. The RDI QA department will assess these platforms on a study-by-study case.

7. Vendor contracting

After the selection of a vendor the appropriate contracts should be put in place prior to commencement of the trial. However, it is acknowledged that some trial set-up activities may be undertaken prior to formal execution of a contract so as not to delay study progress against milestones. In this instance, a 'letter of intent' outlining the specific set-up activities, standards to adhere to and timelines must be put in place. **To be clear, study start-up does not include shipment of IMP, trial specific screening or dosing.**

Contracts should clearly detail:

- The delegated tasks, duties and functions between the parties.
- The required standards of service.
- The process for further subcontracting by the vendor to ensure that subcontracting does not go ahead without the sponsor's knowledge and approval.

Contracts will be prepared according to **R&D Working Instruction 40, Contract & Agreement Preparation.**

Once a contract is in place the sponsor must ensure that it remains current and that the requirements of the contract are being met by all parties.

At study set up it should be defined what will trigger the review of the contract. These triggers could be protocol amendments, updates to legislation and changes in sponsor processes.

Insufficient oversight of contracts can result in:

- No contract in place with a vendor.
- A contract in place after the study activities have begun.
- An organisation not fulfilling its contractual obligations
- Study activities continuing after the contract has expired.
- Additional study activities being undertaken without a contract amendment.

8. Sponsor Oversight of Vendor

Maintaining oversight of the vendor should be done via regular contact.
This may include:

- Emails
- Teleconferences
- Site visits
- Independent audits
- Review of agreed deadlines and contractual milestones.

The oversight must be proportionate to the activity undertaken as well as the initial and on-going risk assessment made by the sponsor.

Oversight correspondence must be documented and held in the TMF.

RDI QA must provide the vendor with all the appropriate documentation to enable them to provide the service they are contracted to do (i.e. copies of the protocol and any subsequent amended protocol, updated SmPCs).

A clear ‘two-way’ communication and update process should be established so that any changes originating from both parties regarding the delivery, management or oversight can be risk assessed and formally agreed.

An escalation process must be in place to ensure any identified non-compliance or performance issues can be assessed and dealt with.

9. Implementation

Implementation of this SOP will conform to the process outlined in R&D SOP 01 Management of SOPs.